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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,391	11/14/2001	Kiamars Hajizadeh	3873 P 010	4943

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,391	HAJIZADEH ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed October 29, 2004 is acknowledged and has been entered. Also the clean copy of the declaration submitted October 29, 2004 is acknowledged and has been entered and therefore Examiner has removed the objection to the declaration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, part (b) the recitation "substantially" is vague and indefinite. It is unclear what is considered to be substantial. There is no definition provided for the term in the specification. See also deficiency found in claim 16.

Claim 11 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim recites determining the presence of pathogenic prion protein whereas the body of the claim recites determining the presence or concentration of the pathogenic prion protein. The preamble of the claim does not recite "concentration". It is recommended to delete the term from the body of the claim or add the term to the preamble of the claim. In the event Applicant amends the claim to add the term to the preamble of the claim, Applicant is advised to show support in the specification for the term. See also deficiency found in claim 28.

Claim 34 is vague and indefinite because it is unclear what animal part applicant is referring to. There is no definition provided for the term in the specification.

Claim 35, part (c) "analyzing the test device" is vague and indefinite. It is unclear what Applicant intends. Is applicant detecting the labeled antibody captured in a detection region or is Applicant reviewing some other part of the device to determine the presence of the prion protein. Please clarify.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3, 7-17, 19, 27, 28, 32-36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmerr et al (US 6,150,172) in view of Sundrehagen (WO 00/36418) and further in view of Pugia et al (US 5,846,754).

Schmerr et al disclose methods for selectively detecting abnormal prion protein in a sample. Schmerr et al disclose that the detection can be performed by immunoassays such as ELISA and sandwich immunoassays (col 8-10). Schmerr et al specifically teaches that extraction solvent containing any prion protein can be applied to an immunochromatographic membrane or support (col 10, lines13-25). Schmerr et al disclose the use of antibodies in these immunoassays. Schmerr et al disclose that the detection can be performed using an immunochromatographic membrane or support (test device). Schmerr et al disclose that the sample can be a biological sample or products made from animal organs or tissues such as food and processed food products (col 5). Schmerr et al disclose that the sample can be homogenized (col 5). Schmerr et al disclose treating the sample with proteinase K to digest the normal host prion. Schmerr et al also disclose the extraction of prion protein into a buffered medium. Schmerr et al disclose that abnormal prion proteins include proteins found in transmissible spongiform encephalopathy, Kuru and Creutzfeld-Jakob Disease (col 6).

Schmerr et al differ from the instant invention in failing to teach the specifics of the immunochromatographic membrane (test device).

Sundrehagen (WO 00/36418) disclose a test device for detecting and quantifying the content of analyte in a sample. Sundrehagen disclose that the test device comprises a sample pad, which comprises a reagent for removing variants of analyte which are not desired to be detected. Sundrehagen disclose that the test strip also comprises a conjugate pad having a labeled first antibody and a detection pad (test strip) comprising an immobilized second antibody (Fig. 1). Sundrehagen disclose that detection can be visual or with the aid of instrumentation (p. 25-26). Sundrehagen also discloses the use of a calibration curve to determine the analyte (p. 31).

It would have been obvious to one of ordinary skill in the art to use the test device taught by Sundrehagen in the method of Schmerr et al because Schmerr et al specifically teaches the advantages of using test strips and Sundrehagen et al shows that their device provides for different variant forms of an analyte to be discriminated and that by measuring different variants of a protein in a sample of interest, a diagnosis or assessment of a disease or cellular damage can be made.

Schmerr et al and Sundrehagen et al differ from the instant invention in failing to teach proteinase-K immobilized in the test device.

Pugia et al (US 5,846,754) disclose impregnating an enzyme in a test strip (col 4).

It also would have been obvious to one of ordinary skill in the art to immobilize proteinase-K in the device of Sundrehagen for use in the method of Schmerr et al because Schmerr et al teaches proteinase-K to remove undesired proteins from the

sample and Sundrehagen et al teaches immobilized reagents in the test device to remove variants of analyte which are not desired to be detected and Pugia et al teaches that it is known in the art to immobilize enzymes to a test device prior to the addition of sample. Therefore, it would have been obvious to one or ordinary skill in the art to immobilize proteinase-K in the device of Sundrehagen for use in the method of Schmerr et al. Further, the immobilization of proteinase-K on the test device provides the advantage of having one less preparation step of the sample.

With respect to the response produced within from about 0.5 to 20 minutes after the sample is applied to the test device. Since, the modified method and device of Schmerr et al comprises the same test device and reagents as instantly recited one of ordinary skill in the art would expect the response to be produced within the time as instantly recited.

7. Claims 6, 18, 20, 21, 29, 30, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmerr et al (US 6,150,172) in view of Sundrehagen (WO 00/36418) and further in view of Pugia et al (US 5,846,754).

See above for teachings of Schmerr et al, Sundrehagen and Pugia et al.

Schmerr et al, Sundrehagen and Pugia et al differ from the instant invention in failing to teach the buffer is an aqueous solution with an ionic strength of from about 200 to about 400 nM. Schmerr et al, Sundrehagen and Pugia et al also fail to teach the amount of enzyme on the solid support and the weight/volume ratio of sample to buffer.

With respect to the ionic strength of the buffer solution as recited in the instant claims, the optimum ionic strength can be determined by routine experimentation and thus would have

been obvious to one of ordinary skill in the art. Further, It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

With respect to the buffer in a weight/volume ratio of sample to buffer as recited in the instant claims the optimum weight/volume ratio of sample to buffer can be determined by routine experimentation and thus would have been obvious to one or ordinary skill in the art. Further, It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

With respect to the amount of enzyme on the solid support as recited in the instant claims the optimum amount of enzyme on the solid support can be determined by routine experimentation and thus would have been obvious to one or ordinary skill in the art. Further, It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Allowable Subject Matter

8. Claims 4, 5, 22-26, 31 and 37 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record neither teaches nor suggests methods for detecting prion protein wherein at least four elements comprised in the buffer for homogenizing the sample (i.e. at least one surfactant or emulsifier, at least one polysaccharide, casein and albumin).

Response to Arguments

10. Applicant's arguments filed October 29, 2004 have been fully considered but they are not persuasive.

With respect to the 112 2nd rejections concerning the recitation "substantially" since Applicant did not directly argue this rejection. The rejection has been maintained.

Applicants argue that the modification of Schmerr et al. in view of Sundrehagen and Pugia et al. in a manner that apparently reconstructs Applicants' invention is improper and insufficient to present a *prime facie* case of obviousness. With respect to Applicants arguments it appears Applicant is arguing hindsight reconstruction. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants argue that Applicants' invention uses a buffer without organic solvents. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., buffer without organic solvents) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read

into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argue that Schmerr et al does not disclose a method for extracting prion protein having instantaneous results. This is not found persuasive because as stated in the previous office action and above. With respect to the response produced within from about 0.5 to 20 minutes after the sample is applied to the test device. Since, the modified method and device of Schmerr et al comprises the same test device and reagents as instantly recited one of ordinary skill in the art would expect the to response to be produced within the time as instantly recited. Further, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that Schmerr et al. fails to teach or suggest any specifics of the immunochromatographic membrane test device. This is not an argument because as stated in the previous office action and above Examiner has not relied upon Schmerr et al. for these teachings. Examiner has relied upon Sundrehagen for teaching the specifics of the device. Further, as stated in the previous office action and above Schmerr et al specifically teaches the advantages of using test strips and Sundrehagen et al shows that their device provides for different variant forms of an analyte to be discriminated and that by measuring different variants of a protein in a sample of interest, a diagnosis or assessment of a disease or cellular damage can be made.

Further, as stated above applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Sundrehagen does not teach nor suggest pre-treating the biological sample with proteinase-K to digest the non-pathogenic prion protein. This is not found persuasive because Examiner has not relied upon Sundrehagen for teachings this limitation. Examiner has relied upon Sundrehagen for teaching the specifics of test devices. Schmerr et al. teaches pre-treating with proteinase-K. Once again as stated above applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Pugia et al does not teach or suggest using protease for removing non-pathogenic prion protein. This is not found persuasive because Examiner has not relied upon Pugia et al for this teaching. Examiner has relied upon Pugia et al for teaching that it is known in the art to immobilize a protease on a support.

Applicant argues that the Examiner has not provided specific evidence to support the statement that "Pugia et al. that it is known in the art to immobilize enzyme to a test device prior to the addition of sample". This is not found persuasive because Pugia et al discloses in column 4 that a test strip (device) is impregnated with proteases

prior to the addition of a sample. Pugia et al discloses that the protease is subjected to the device and dried and thus the test strip is impregnated with the protease. One of ordinary skill will recognize that the dried protease held by the absorbent carrier of the test device is immobilized or it would not be contained as part of the device. Therefore, it is Examiner's position that the combination of Schmerr et al. in view of Sundrehagen and Pugia et al. reads on the instantly recited claims.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
December 17, 2004

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12/26/04